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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/027,877	12/19/2001	William Earl Webler	5618P2977	1005
8791	7590	01/24/2006	EXAMINER	
BLAKELY SOKOLOFF TAYLOR & ZAFMAN 12400 WILSHIRE BOULEVARD SEVENTH FLOOR LOS ANGELES, CA 90025-1030			FOREMAN, JONATHAN M	
		ART UNIT		PAPER NUMBER
				3736

DATE MAILED: 01/24/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>
	10/027,877	WEBLER, WILLIAM EARL
	<b>Examiner</b>	<b>Art Unit</b>
	Jonathan ML Foreman	3736

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 28 October 2005.
- 2a) This action is FINAL.                            2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-20 and 26 is/are pending in the application.
  - 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 1-20 and 26 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) All    b) Some \* c) None of:
    1. Certified copies of the priority documents have been received.
    2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                     | Paper No(s)/Mail Date. _____ .  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ . | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
|  | 6) <input type="checkbox"/> Other: _____ .                                  |

## DETAILED ACTION

### *Continued Examination Under 37 CFR 1.114*

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 10/11/05 has been entered.

### *Claim Rejections - 35 USC § 103*

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 1 – 3, 5 – 9, 11, 12, 14 – 20 and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,063,085 to Tay et al. in view of U.S. Patent No. 6,539,792 to Lull et al.

In regards to claims 1 – 3, 5 – 9, 11, 12, 14 – 20 and 26, Tay et al. discloses an elongate member as a needle, in that Tay et al. discloses the probe as a hollow elongated member (Col. 20, lines 12 – 18), or rod insertable into a body; a thermally conductive heating element coupled to the distal portion of the elongate member, the heating element comprising a wire whose electrical resistance changes in response to a change in temperature (Col. 20, lines 45 – 49). The needle includes a distal opening, and a lumen (148; Figure 21) extending from a proximal end to the distal opening (Col. 16, lines 12 – 15) in communication with the distal opening capable of allowing a

substance to be delivered through the lumen. The distal end of the needle is capable of puncturing skin (Col. 15, line 65 – Col. 16, line 1). Tay et al. discloses anemometry circuitry and comparing a first resistance and a second resistance of the at least one heating element to indicate a change of conditions related to a distance of penetration of the heating element (Col. 20, lines 48 – 54). Tay et al. discloses an outer diameter between 0.009 inches and 0.134 inches (Col. 19, line 56 – Col. 20, line 18). The heating element is less than the thickness of the tissue in which it is inserted. In order to operate the device as disclosed by Tay et al. must include a first and second lead coupled to the at least one heating element. However, Tay et al. fails to disclose the anemometry circuitry comprising the heating element and a variable resistor as resistive circuit element. Nor does Tay et al. disclose an amplifier coupled to the circuit to amplify the voltage difference sensed between the heating element and the variable resistor, and to input the voltage difference back to the circuit to modify the temperature of the heating element such that the heating element assumes a second resistance. Lull et al. teaches a circuit for use in a constant temperature anemometer (Col. 17, lines 10 - 15) comprising a balanced circuit (Col. 11, lines 40 – 46) having the heating element ( $R_1$ ,  $R_2$ ) and a variable resistor (Col. 7, lines 49 - 52) as resistive circuit element and an amplifier coupled to the circuit to amplify the voltage difference sensed between the heating element and the variable resistor, and to input the voltage difference back to the circuit to modify the temperature of the heating element such that the heating element assumes a second resistance (Col. 7, line 25 – Col. 8, line 22). Lull et al. discloses anemometry circuitry separately coupled to each of the heating elements. It would have been obvious to one having ordinary skill in the art to modify the circuitry as disclosed by Tay et al. to include an interface to the balanced circuit as disclosed by Lull et al. in order to compare variations in the resistance of the heating elements (Col. 17, lines 10 – 15). Tay et al. fails to disclose the heating element being between 0.010 inches and 0.400 inches. However, a

change in the size of a prior art device is a design consideration within the skill of the art. In re Rose, 220 F.2d 459, 105 USPQ 237 (CCPA 1955). In Gardner v. TEC Systems, Inc., 725 F.2d 1338, 220 USPQ 777 (Fed. Cir. 1984), cert. denied, 469 U.S. 830, 225 USPQ 232 (1984).

4. Claims 4 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,063,085 to Tay et al. in view of U.S. Patent No. 6,539,792 to Lull et al. as applied to claims 2 and 11 above, and further in view of U.S. Patent No. 3,470,604 to Zenick.

In reference to claims 4 and 13, Tay et al. in view of Lull et al. discloses a needle, but fails to disclose the needle being formed of stainless steel. However, stainless steel is well known in the medical industry for its strength, durability, ease of sterilization etc. Zenick discloses a hypodermic needle that is formed of stainless steel (Col. 1, line 65). It would have been obvious to one having ordinary skill in the art at the time the invention was made to form the needle as disclosed by Tay et al. in view of Lull et al. out of stainless steel as taught by Zenick in order to have a sturdy, durably and easily sterilized hypodermic needle for insertion into a patient.

5. Claims 10 and 18 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,063,085 to Tay et al. in view of U.S. Patent No. 6,539,792 to Lull et al. as applied to claims 1 and 14 above, and further in view of U.S. Patent No. 5,873,835 to Hastings et al.

6. In regards to claims 10 and 18, Tay et al. in view of Lull et al. fails to disclose the forming the elongate member of an electrically conductive material and coupling the first end of the heating element to an electrically conductive lead and coupling the second end of the heating element by the elongate member. Hastings et al. teaches a portion of the elongate member being electrically conductive and the anemometry circuitry interface comprising an electrically conductive lead electrically coupled to a first end of the heating element, and the elongate member electrically

coupled to a second end of the heating element (Col. 11, lines 33 – 35). It would have been obvious to one having ordinary skill in the art at the time the invention was made to form the elongate member as disclosed by Tay et al. in view of Lull et al. to be an electrically conductive material and coupling the first end of the heating element to an electrically conductive lead and coupling the second end of the heating element by the elongate member as taught by Hastings et al. in order to reduce the resistance of the electrical connections to the heating element (Col. 11, lines 33 – 35).

*Response to Arguments*

Applicant's arguments filed 10/11/05 have been fully considered but they are not persuasive. Applicant asserts that although Tay et al. allows for the possibility of blood flowing out of the puncture in the vessel and through the insulation layer and out of hole, Tay et al. does not teach or suggest a distal opening, and a lumen extending from a proximal end to the distal opening in communication with the distal opening to allow a substance to be delivered through the lumen and out of the opening. However, it is well established that a recitation with respect to the manner in which an apparatus is intended to be employed, i.e., a functional limitation, does not impose any structural limitation upon the claimed apparatus which differentiates it from a prior art reference disclosing the structural limitations of the claim. *In re Pearson*, 494 F.2d 1399, 181 USPQ 641 (CCPA 1974); *In re Casey*, 370 F.2d 576, 152 USPQ 235 (CCPA 1967); *In re Otto*, 312 F.2d 937, 136 USPQ 458 (CCPA 1963). Where the prior art reference is inherently capable of performing the function described in a functional limitation, such functional limitation does not define the claimed apparatus over such prior art reference, regardless of whether the prior art reference explicitly discusses such capacity for performing the recited function. *In re Ladtke*, 441 F.2d 660, 169 USPQ 563 (CCPA 1971). In addition, where there is reason to believe that such functional limitation may

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be an inherent characteristic of the prior art reference, Applicant is required to prove that the subject matter shown in the prior art reference does not possess the characteristic relied upon. *In re Spada*, 911 F.2d 705, 15 USPQ2d 1655 (Fed. Cir. 1990); *In re King*, 801 F.2d 1324, 1327, 231 USPQ 136, 138 (Fed. Cir. 1986); *In re Ludtke*, 441 F.2d 664, 169 USPQ 566 (CCPA 1971). In the present case, the lumen (148; Figure 21) extending from a proximal end to the distal end (Col. 16, lines 12 – 15) in communication with the distal opening disclosed by Tay et al. is fully capable of allowing a substance to be delivered through the lumen and out of the opening. Applicant asserts that the distal end of the elongate member as disclosed by Tay et al. is not capable of puncturing skin. However the examiner disagrees. Provided enough force, a blunt object is capable of puncturing skin.

*Conclusion*

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jonathan ML Foreman whose telephone number is (571)272-4724. The examiner can normally be reached on Monday - Friday 8:00 am - 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571)272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

JMLF

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